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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,639

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Thomas J. Fogarty

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08/02/2006

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/646,639

Applicant(s)

FOGARTY ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-65,74,75 and 92-118 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,9,10,14-21,24,29-31,34,41,51-54,56,74,92-95,97-112,114 and 115 is/are rejected.
- 7) ☒ Claim(s) 32,37-39,96,113 and 116-118 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>various</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-5, 11-13, 22, 23, 25-28, 33, 35, 36, 40, 42-50, 55, 57-65 and 75.

***Election/Restrictions***

Claims 3, 4, 5, 11-13, 22, 23, 25-27, 28, 33, 35, 36, 40, 42-50, 55, 57-65 and 75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 22, 2006.

Even though not included in Applicants' list of withdrawn claims, claims 22 and 28 were also withdrawn from consideration as being drawn to non-elected species because the elected species (Figure 49) is not a friction lock but an interference lock; note that page 29, which describes Figure 49, makes no mention of friction or a friction lock.

Similarly, claim 75 has been withdrawn because it sets forth that the attachment device is located on an outer radial side of the gasket body. Since the elected species (Figure 25) does not have the attachment device on the outer radial side of the gasket body, the Examiner concluded that this claim is drawn to a non-elected invention also.

In the response filed May 22, 2006, Applicants failed to identify copending applications and support for new or amended claims. Applicants are respectfully requested to provide such information in response to this Office action or the response may be held non-responsive.

***Drawings***

Figure 1 to 3 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid

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abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

In claims 92, 107, 109, 115, and 117, the terms "shelf" and "slope" are not used in the specification to describe the device and thus it is unclear what element of the claim language corresponds to the disclosed invention of elected species Figure 25.

### ***Claim Objections***

Claims 51-53, 74, 93, and 98-100 are objected to because of the following informalities:

The preambles are drawn to "a device for connecting a heart valve to a first mass", but the bodies of these claims positively recite the heart valve. For this reason, there is an inconsistency between the preamble and the claim body that makes it unclear whether the heart valve is positively required. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 74 and 101 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claims 74 and 101, there is no original support for a fabric covering over the flange or sewing ring of Figure 25 so this appears constitute new matter with respect to the original specification; see page 21 of the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The manner of claiming the flange as a separate element from the sewing ring in confusing in view of the invention as disclosed since the flange and sewing ring are essentially the same portion of the device as disclosed.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 9, 10, 15-21, 24, 29, 34, 41, 51-54, 56, 92-95, 97-112 and 114-115 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffin et al (US 6,241,765). Griffin anticipates the claim language where the gasket as claimed is the stiffening ring (29) (see Figure 3) of Griffin, the sewing ring and/or skirt as claimed is the fabric (80) and/or shoulder (57), the attachment device as claimed is the opening (96) (see Figure 7), and the gasket radius as claimed is the inner radius of the stiffening ring; see column 5, line 19 et seq.

With regard to claim 9, the attachment device as claimed includes the pin (91) of Griffin.

With regard to claim 15, the tortuous channel would be provided when the fabric is covering the opening (96).

With regard to claim 29, the can as claimed is the opening (96) of Griffin.

With regard to claim 52, the terminology "biological valve" is interpreted broadly to mean that the valve is designed to be used in a living organism.

With regard to claim 56, the suture as claimed is met by the pin (91) of Griffin in that "suture" has a broad meaning in the art to include such structures.

With regard to claim 95, the "filament" as claimed is considered to be broad enough of a term to read on the pin (91) of Griffin.

With regard to claim 108, the term "crown" is interpreted to be broad enough to read on the valve (14) of Griffin.

Claims 1, 2, 9, 10, 14-21, 24, 29-31, 34 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Peterson et al (US 2003/0109922). Peterson anticipates the claim language where the gasket as claimed is the stent (16) and sewing ring (18) of Peterson, and the attachment device as claimed is hole (24) (see Figures 2 to 6, 11, and 13 of Peterson).

With regard to claim 15, the fabric sewing ring (18) of Griffin provides the tortuous channel as claimed.

#### ***Allowable Subject Matter***

Claims 32, 37-39, 96, 113, and 116-118 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

**Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.**

**Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic  
Primary Examiner  
Art Unit 3738